Appl. No. 09/783,253 Amdt. dated June 27, 2003 Amendment under 37 CFR 1.116 Expedited Procedure Examining Group

## REMARKS/ARGUMENTS

In the Office Action, the Examiner noted that: Claims 1-111 are pending in the application, of which Claims 1-77 and 80-101 are withdrawn from consideration, claims 78, 79 and 102-105, 107, 108, and 111 are rejected, and Claims 106, 109, and 110 were objected to and not treated on the merits.

By the present amendment Claims 78, 102-106, and 110have been amended.

Thus, Claims 1-111 are pending of which Claims 1-77 and 80-101 are withdrawn from consideration, and Claims 78, 79, and 102-111 are under consideration. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

## Response to Office Action Paragraphs 2 & 3 Claim Objection

In the Office Action Examiner objected to Claims 106, 109, and 110 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent Claim. By the present amendment, Claim 106 and 110 have been amended. Applicant believes that the amendment obviates the rejection and request consideration of the Claims.

In the Office Action Examiner objected to Claims 103-105 stating that "in claims 103-105, the claims read 'A method as in any of claims 102." and suggested that the claim language should read as, "A method as in claim 102." By the present amendment, Claims 103-105 have been amended to incorporate Examiner's suggestion. Applicant believes that the amendment obviates the rejection and request consideration of the Claims.

## Response to Office Action Paragraphz 4-4 Claim Rejection Under 35 U.S.C. §102

In the Office Action Examiner rejected Claims 78, 79, 102-105, 107, 108, and 111 under 35 U.S.C. §102(e) as being anticipated by Ragheb (U.S. Patent 6,299,604).

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In rejecting the claims, Examiner stated that "Ragheb discloses a coated implantable medical device (10) comprising a bioactive layer (18) and limiting barrier (20) as is claimed (figures 1-5 and 8-12, column 6 lines 41-67, column 7 lines 15-54, column 8 lines 6-20, column 9 lines 27-67, column 10 lines 1-55, column 11 lines 5-24 and 44-59, column 12 lines 1-33 and 53-67, column 13 lines 1-52, column 14 lines 56-67, column 22 lines 19-51 and 60-67 and column 23 lines 1-34).

Ragheb is generally directed to a coated implantable implantable medical device (10) comprising a bioactive layer (18) and a porous limiting barrier (20).

By the present amendment, Claim 78 has been amended to recite, among other things: "...so that the substance is released from the prosthesis at multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate and begins after an appreciable preselected time period."

In contrast to the present invention, Ragheb does not disclose release of the substance at "at multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate." Applicants have reviewed the disclosure of Ragheb and that cited by the Examiner above, but were unable to find any reference or suggestion regarding the release of the substance as claimed by the Applicants in the Claims as presently amended. Ragheb's only disclosure regarding the rate of release for the substance is that of a constant rate of release (please see column 13 lines 1-5, column 14 lines 61-62), or a total quantity released (please see column 13 lines 49-51, column 14 lines 17-18). Rhageb's only disclosure to a non-constant rate of release, is a vague reference to geometric rate of release when the substance is contained in triangular aperture within the stent structure, as shown in FIG. 10D (please see column 22 lines 39-42). Assuming arguendo that this reference provides any teaching at all, such reference given the shape of the aperture (the exposed surface area of the aperture decreasing in size as you move away from the outer surface of the stent) would lead to a decaying rate of release and not "multiple rates including an initial rate and at least one subsequent rate which is substantially higher than the initial rate," as is presently claimed by the Applicant.

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"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." W.L. Gore & Associates v. Garlock, Inc., 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicants respectfully submit that Claim 78 is not anticipated by or obvious in view of Ragheb, and that it is patently distinguishable over the same, and request allowance of the same and all those depending directly or indirectly therefrom.

## CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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